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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,747	03/14/2000	Alberto Reiner	622-39	8132

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,747

Applicant(s)

REINER ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,14,16-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,14,16-23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

The following is in response to the amendment/declaration filed 9/16/02.

Claims 13,14, 16-23 and 25-28 are pending in the case.

All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

Claim Rejections - 35 USC § 102/ Response to Declaration

The rejection of claims 13,14,16-23 and 25-28 under 35 U.S.C. 102(b) as being anticipated by Granger, EP 466650 is maintained for the reasons of record.

Claims 13,14,16-23 and 25-2820-26 are drawn to a method for obtaining an average Cmax of Diclofenac via administration of diclofenac in acid and/or salt form together with sodium/potassium bicarbonates in which the alkali metal bicarbonates are present in an amount of from 20 to 80% by weight of diclofenac.

Granger anticipates the claims as it teaches a pharmaceutical formulation comprising a non-steroidal anti-inflammatory and a metal base or basic salt such as hydroxide, sulfate, carbonate, bicarbonate, subcarbonate, or trisilicate; wherein the nonsteroidal anti-inflammatory may be diclofenac and the alkali metal can be aluminum, sodium, magnesium, potassium or bismuth (pp. 1 and 2). Granger further discloses that the metal base or basic salt may be administered in an amount ranging from about 25 to about 100% (p.2, line 57 - p.3, line 5).

Granger also teaches that the pharmaceutical formulation or composition comprising the non-steroidal anti-inflammatory agent such as diclofenac may be administered in admixture with suitable pharmaceutical diluents, excipients or carriers and that the active drug components may be combined with any oral nontoxic

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pharmaceutically acceptable inert carrier such as lactose, starch, sucrose, etc. Furthermore, that sweetening and flavoring agents and preservatives can also be included where appropriate (p. 3, lines 6-23) anticipating the presence and amount of at least one flavoring substance, be it mint, aniseed and ammonium glycyrrhizinate as these flavoring substances could be adjusted in proportion to suit an appropriate taste. Granger also teaches the use of disintegrating agents such as methylcellulose and cross-linked PVP (p.3, lines 16-23) which anticipate the use of immediate and delayed release layers.

Granger discloses that the metal base or basic salt is co-administered with fenamic acid derivatives or non-steroidal systemic anti-inflammatory agents to confer a cytoprotective effect or reduce the gastrointestinal inflammation associated with administration of these agents (p.2, lines 20-58).

Although Granger does not explicitly teach the T_{max} and C_{max} values, the T_{max} and C_{max} values are a function of administering the diclofenac with the metal base or basic salt wherein the concentration of the metal base or basic salt is 20-80% by weight; thus, given that Granger teaches administration of diclofenac or fenamic acid derivatives with a metal base or basic salt wherein the concentration of the basic salt is analogous to that of applicant, 25%-100%, the T_{max} and C_{max} values would be inherently achieved.

Applicant's chief argument is that the teachings of Granger do not anticipate applicant's discovery of the T_{max} and C_{max} values because the dissolution profile for that of the bicarbonate form is significantly greater than that of the 4 other metal basic salt forms taught by Granger. Applicant has submitted a declaration to purportedly support the unexpected advantage of the invention. The declaration filed under 37 CFR 1.132 filed

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9/16/02 is insufficient to overcome the rejection of claims 13,14,16-23 and 25-28 based upon Granger, EP 0466650 as set forth in the last Office action.

The declaration attempts to show that even though one of skill in the art would recognize that Granger teaches a diclofenac composition with sodium or potassium bicarbonate, one of skill in the art could not expect the dissolution profile of sodium/potassium bicarbonate to be exemplary of all the metal basic salts disclosed by Granger since there are 5 additional basic salts and 3 additional metals disclosed. However, applicant only compares two other metal basic salts with sodium bicarbonate, magnesium/calcium carbonate and aluminum hydroxide. The data presented on p. 3 of the declaration actually shows that the carbonate dissolution profile is comparable to the bicarbonate form. The aluminum hydroxide form has a lower dissolution profile, however, this does not overcome the fact that Granger teaches the use of sodium bicarbonate as one of the more effective metal basic salt to be used with a non-steroidal anti-inflammatory. Granger teaches in Example 2 that sodium bicarbonate demonstrated the greatest change in the reduction of ulcer formation when co-administered with a non-steroidal anti-inflammatory. Thus the prior art has established the motivation for using the sodium bicarbonate form with a non-steroidal anti-inflammatory such as the fenamic acid derivative of diclofenac.

If the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, the disclosure should be regarded as sufficient. Failure to appreciate a result is of no import if the result is a necessary consequence of what was deliberately intended, *Mehl/Biophile Int. Corp. v. Milgram*, U.S. C.A.F.C., 52 USPQ2d 1303. Since Granger not only teaches the co-administration of sodium bicarbonate with a fenamic acid derivative in the claimed concentration range and demonstrates that the sodium bicarbonate form is one

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of the more effective basic salt forms of those disclosed to be co-administered with a fenamic acid derivative, applicant's discovery that there is a dissolution profile associated with administering diclofenac with the same metal basic salt in the same concentration is seen as the recognition of an inherent effect associated with that administration.

For the reasons set forth above, the 35 U.S.C. 102 (b) rejection is maintained.

Interview Summary

It should be noted that the the interview summary of September 6, 2002 only states that evidence was presented by applicant's attorney and that a declaration would be submitted for more favorable consideration. The examiner did not agree that there was sufficient evidence to overcome the rejection of record at the time of the interview. The interview summary reflects that the examiner acknowledged the presentation of the evidence and the purpose for applicant's representative demonstrating the evidence.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.